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*IN THE UNITED STATES PATENT AND TRADEMARK OFFICE*

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| Applicants: | Nicholas BARDEN et al. |
| Title: | MEANS AND METHODS FOR DIAGNOSING AND TREATING AFFECTIVE DISORDERS |
| Appl. No.: | 10/825,593 |
| Filing Date: | 04/16/2004 |
| Examiner: | Michael D. Pak |
| Art Unit: | 1646 |
| Confirmation No. | 7794 |

**DECLARATION UNDER 37 CFR § 1.132**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned, Professor Dr. Norbert Müller, declares the following:

1. I received my Ph.D. degree in Clinical Psychology from the University of Munich, Germany, in 1975, and my MD. degree from the University of Munich, Germany, in 1983. I have been working in the field of psychiatry since 1982. A copy of my resume is attached as Exhibit A2.

2. I am currently the head of the Psychoneuroimmunology Research Group at the Psychiatry and Psychotherapy Hospital of the Ludwig-Maximilians University in Munich, Germany. I have published more than 250 scientific articles in the field of psychiatry.

3. I understand that the U.S. Patent and Trademark Office has cited U.S. Patent No. 6,323,236 B2 to McElroy against the claimed invention of the present application in the Office Actions

dated January 7, 2008, and July 11, 2008. I have read the Office Actions in this application and the cited reference. In this regard, I understand that the U.S. Patent and Trademark Office's position is that McElroy anticipates the claimed invention, because the references teaches a method comprising the administration of tenidap for the treatment of Impulse Control Disorders (ICDs) and reports the hypothesis that ICDs may be related to mood disorder or may be forms of affective spectrum disorder, a hypothesized family of disorders that share at least one common physiologic abnormality with major depression.

4. I submit this declaration to establish that Impulse Control Disorders (ICDs) encompass medical indications that are different from depression and other mood disorders, as evidenced herein.

5. I assert that the main feature of ICDs is impulsivity, which is generally defined as acting without thinking or as behaving recklessly with no regard for any consequences. Among the characteristics normally observed in ICD patients are repetitive or compulsive engagement in a behaviour despite harmful consequences, reduced control over this problematic behaviour, a state of craving or urge prior to engagement in the problematic behaviour, and a hedonic feeling during the performance of the problematic behaviour. Examples of ICDs include kleptomania, binge eating disorder, pathological gambling, and intermittent explosive disorder.

6. I state that contrary to ICDs, the essential features of depression are a depressed mood and/or loss of interest or pleasure in nearly all activities for a period of at least two weeks. During a depressive episode, a patient will state that he or she is sad, hopeless, and discouraged. Additional features of depression include a lack of pleasure or enjoyment in hobbies or any other activities previously considered pleasurable, and changes in appetite and sleep patterns.

7. I state that the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR), published by the American Psychiatric Association, provides diagnostic criteria for each mental disorder and defines the various categories of mental disorders.

8. I assert that DSM-IIV-TR classifies depression as a mood disorder (*see* diagnostic code 296.2X; attached herein as Exhibit B2), and assigns ICDs with their own classification, which is independent and distinct from mood disorders (*see* diagnostic code 312.3X; attached herein as Exhibit C2).

9. I state that the Handbook of Psychiatric Measures, also published by the American Psychiatric Association, recommends that ICDs be assessed using measurements such as the Barratt Impulsiveness Scale (BIS-11); the Anger, Irritability, and Assault Questionnaire (AIAQ); the Buss-Durkee Hostility Inventory (BDHI); the South Oaks Gambling Screen (SOGS); and the Massachusetts General Hospital (MGH) Hairpulling Scale (*see* Exhibit D2).

10. I further state that the Handbook of Psychiatric Measures recommends that depression be assessed using the Hamilton Rating Scale for Depression (HamD); the Montgomery-Asberg Depression Rating Scale (MADRS); the Beck Depression Inventory (BDI); and the Inventory of Depressive Symptomatology (IDS) among others (*see* Exhibit E2). The different assessment scales used for ICDs and depression clearly show that ICDs and depression are separate and distinct disorders.

11. I assert that a 16-week, multi-centered, randomized, placebo-controlled, flexible-dosing, double-blind study investigating the effects of antidepressants in the treatment of ICDs found that paroxetine and placebo group had comparable improvement gambling behaviour (*see* Grant *et al.*, 2003, *Int. Clin. Psychopharmacol. 18*: 243–249; attached herein as Exhibit F2). This clinical study was performed on individuals with no or minimal depressive or anxious symptoms, further supporting the fact that ICDs and depression are distinct psychiatric disorders.

12. I state that the evidence presented herein clearly establishes that ICDs are different and distinct from depression and other mood disorders.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

München, 16.10.08 Norbert Müller

Date Prof. Dr. Norbert Müller

# EXHIBIT A2

Exhibit A2

**Curriculum Vitae Prof. Dr. med. Dipl.-Psych. Norbert Müller**

| | |
|---|---|
| 1949 | 9.9. Born in Berlin |
| 1969- | Study of Psychology, University of Munich |
| 1975 | Ph. D. in Clinical Psychology (Diplom-Psychologe) |
| 1975- | Study of Medicine, University of Munich, |
| 1981 | Medical State Examination, Medical Registration |
| 1983 | Doctorate in Medicine with the thesis '*Zur Wirksamkeit von Trazodone bei endogen depressiven Patienten' (magna cum laude)* *(Efficacy of Trazodone in endogenous-depressed patients).* |
| 1982- | Medical assistant at the psychiatric hospital, University of Munich (Direktor Prof.Dr.H.Hippius) |
| 1988 | (Head: Prof. Dr. H. Hippius) |
| 1985 | Psychiatric consultant, advisory center of the public health department, city of Munich |
| 1988 | Scientific assistant, department of neurochemistry, University of Munich |
| 1989 | Medical assistant at the Dep. of Neurology, University of Munich (Head: Prof. Dr. Th. Brandt) |
| 1990 | Specialist in Neurology and Psychiatry<br>Specialist in Psychotherapy |
| 1990 | Senior psychiatrist, Psychiatric Hospital, University of Munich |
| 1993 | Postdoctoral qualification (Habilitation) at the University of Munich with the thesis: *Psychoneuroimmunologische Untersuchungen bei Patienten mit endogenen Psychosen (Psychoneuroimmunological investigations in patients with endogenous psychoses)* |
| 2000 | Professor of Psychiatry |

Current Affilation: Leitender Oberarzt (Vize-Chair)
Senior Psychiatrist and Lecturer, Psychiatric Hospital, University of Munich

Current Research Activities:
- Psychoneuroimmunology
- Biology and psychopathology in Tourette's syndrome
- Schizophrenia
- Psychopharmacology and atypical antipsychotics

More than 250 publications in the field

# EXHIBIT B2

Exhibit B2



# Mood Episodes

## Major Depressive Episode

### Episode Features

The essential feature of a Major Depressive Episode is a period of at least 2 weeks during which there is either depressed mood or the loss of interest or pleasure in nearly all activities. In children and adolescents, the mood may be irritable rather than sad. The individual must also experience at least four additional symptoms drawn from a list that includes changes in appetite or weight, sleep, and psychomotor activity; decreased energy; feelings of worthlessness or guilt; difficulty thinking, concentrating, or making decisions; or recurrent thoughts of death or suicidal ideation, plans, or attempts. To count toward a Major Depressive Episode, a symptom must either be newly present or must have clearly worsened compared with the person's preepisode status. The symptoms must persist for most of the day, nearly every day, for at least 2 consecutive weeks. The episode must be accompanied by clinically significant distress or impairment in social, occupational, or other important areas of functioning. For some individuals with milder episodes, functioning may appear to be normal but requires markedly increased effort.

The mood in a Major Depressive Episode is often described by the person as depressed, sad, hopeless, discouraged, or "down in the dumps" (Criterion A1). In some cases, sadness may be denied at first, but may subsequently be elicited by interview (e.g., by pointing out that the individual looks as if he or she is about to cry). In some individuals who complain of feeling "blah," having no feelings, or feeling anxious, the presence of a depressed mood can be inferred from the person's facial expression and demeanor. Some individuals emphasize somatic complaints (e.g., bodily aches and pains) rather than reporting feelings of sadness. Many individuals report or exhibit increased irritability (e.g., persistent anger, a tendency to respond to events with angry outbursts or blaming others, or an exaggerated sense of frustration over minor matters). In children and adolescents, an irritable or cranky mood may develop rather than a sad or dejected mood. This presentation should be differentiated from a "spoiled child" pattern of irritability when frustrated.

Loss of interest or pleasure is nearly always present, at least to some degree. Individuals may report feeling less interested in hobbies, "not caring anymore," or not feeling any enjoyment in activities that were previously considered pleasurable (Criterion A2). Family members often notice social withdrawal or neglect of pleasurable avocations (e.g., a formerly avid golfer no longer plays, a child who used to enjoy soccer finds excuses not to practice). In some individuals, there is a significant reduction from previous levels of sexual interest or desire.

Appetite is usually reduced, and many individuals feel that they have to force themselves to eat. Other individuals, particularly those encountered in ambulatory settings, may have increased appetite and may crave specific foods (e.g., sweets or other carbohydrates). When appetite changes are severe (in either direction), there

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may be a significant loss or gain in weight, or, in children, a failure to make expec
weight gains may be noted (Criterion A3).

The most common sleep disturbance associated with a Major Depressive Episo
is insomnia (Criterion A4). Individuals typically have middle insomnia (i.e., wak
up during the night and having difficulty returning to sleep) or terminal insomn
(i.e., waking too early and being unable to return to sleep). Initial insomnia (i.e., d
ficulty falling asleep) may also occur. Less frequently, individuals present with ov
sleeping (hypersomnia) in the form of prolonged sleep episodes at night or increase
daytime sleep. Sometimes the reason that the individual seeks treatment is for the di
turbed sleep.

Psychomotor changes include agitation (e.g., the inability to sit still, pacing, hand
wringing; or pulling or rubbing of the skin, clothing, or other objects) or retardatio
(e.g., slowed speech, thinking, and body movements; increased pauses before an
swering; speech that is decreased in volume, inflection, amount, or variety of content
or muteness) (Criterion A5). The psychomotor agitation or retardation must be sever
enough to be observable by others and not represent merely subjective feelings.

Decreased energy, tiredness, and fatigue are common (Criterion A6). A perso
may report sustained fatigue without physical exertion. Even the smallest tasks seem
to require substantial effort. The efficiency with which tasks are accomplished may
be reduced. For example, an individual may complain that washing and dressing in
the morning are exhausting and take twice as long as usual.

The sense of worthlessness or guilt associated with a Major Depressive Episode
may include unrealistic negative evaluations of one's worth or guilty preoccupations
or ruminations over minor past failings (Criterion A7). Such individuals often mis-
interpret neutral or trivial day-to-day events as evidence of personal defects and have
an exaggerated sense of responsibility for untoward events. For example, a realtor
may become preoccupied with self-blame for failing to make sales even when the
market has collapsed generally and other realtors are equally unable to make sales.
The sense of worthlessness or guilt may be of delusional proportions (e.g., an individ-
ual who is convinced that he or she is personally responsible for world poverty).
Blaming oneself for being sick and for failing to meet occupational or interpersonal
responsibilities as a result of the depression is very common and, unless delusional,
is not considered sufficient to meet this criterion.

Many individuals report impaired ability to think, concentrate, or make decisions
(Criterion A8). They may appear easily distracted or complain of memory difficulties.
Those in intellectually demanding academic or occupational pursuits are often unable
to function adequately even when they have mild concentration problems (e.g., a
computer programmer who can no longer perform complicated but previously man-
ageable tasks). In children, a precipitous drop in grades may reflect poor concentra-
tion. In elderly individuals with a Major Depressive Episode, memory difficulties may
be the chief complaint and may be mistaken for early signs of a dementia ("pseudo-
dementia"). When the Major Depressive Episode is successfully treated, the memory
problems often fully abate. However, in some individuals, particularly elderly per-
sons, a Major Depressive Episode may sometimes be the initial presentation of an ir-
reversible dementia.

Frequently there may be thoughts of death, suicidal ideation, or suicide attempts
(Criterion A9). These thoughts range from a belief that others would be better off if

the person were dead, to transient but recurrent thoughts of committing suicide, to actual specific plans of how to commit suicide. The frequency, intensity, and lethality of these thoughts can be quite variable. Less severely suicidal individuals may report transient (1- to 2-minute), recurrent (once or twice a week) thoughts. More severely suicidal individuals may have acquired materials (e.g., a rope or a gun) to be used in the suicide attempt and may have established a location and time when they will be isolated from others so that they can accomplish the suicide. Although these behaviors are associated statistically with suicide attempts and may be helpful in identifying a high-risk group, many studies have shown that it is not possible to predict accurately whether or when a particular individual with depression will attempt suicide. Motivations for suicide may include a desire to give up in the face of perceived insurmountable obstacles or an intense wish to end an excruciatingly painful emotional state that is perceived by the person to be without end.

A diagnosis of a Major Depressive Episode is not made if the symptoms meet criteria for a Mixed Episode (Criterion B). A Mixed Episode is characterized by the symptoms of both a Manic Episode and a Major Depressive Episode occurring nearly every day for at least a 1-week period.

The degree of impairment associated with a Major Depressive Episode varies, but even in mild cases, there must be either clinically significant distress or some interference in social, occupational, or other important areas of functioning (Criterion C). If impairment is severe, the person may lose the ability to function socially or occupationally. In extreme cases, the person may be unable to perform minimal self-care (e.g., feeding or clothing self) or to maintain minimal personal hygiene.

A careful interview is essential to elicit symptoms of a Major Depressive Episode. Reporting may be compromised by difficulties in concentrating, impaired memory, or a tendency to deny, discount, or explain away symptoms. Information from additional informants can be especially helpful in clarifying the course of current or prior Major Depressive Episodes and in assessing whether there have been any Manic or Hypomanic Episodes. Because Major Depressive Episodes can begin gradually, a review of clinical information that focuses on the worst part of the current episode may be most likely to detect the presence of symptoms. The evaluation of the symptoms of a Major Depressive Episode is especially difficult when they occur in an individual who also has a general medical condition (e.g., cancer, stroke, myocardial infarction, diabetes). Some of the criterion items of a Major Depressive Episode are identical to the characteristic signs and symptoms of general medical conditions (e.g., weight loss with untreated diabetes, fatigue with cancer). Such symptoms should count toward a Major Depressive Episode except when they are clearly and fully accounted for by a general medical condition. For example, weight loss in a person with ulcerative colitis who has many bowel movements and little food intake should not be counted toward a Major Depressive Episode. On the other hand, when sadness, guilt, insomnia, or weight loss are present in a person with a recent myocardial infarction, each symptom would count toward a Major Depressive Episode because these are not clearly and fully accounted for by the physiological effects of a myocardial infarction. Similarly, when symptoms are clearly due to mood-incongruent delusions or hallucinations (e.g., a 30-pound weight loss related to not eating because of a delusion that one's food is being poisoned), these symptoms do not count toward a Major Depressive Episode.

By definition, a Major Depressive Episode is not due to the direct physiological effects of a drug of abuse (e.g., in the context of Alcohol Intoxication or Cocaine Withdrawal), to the side effects of medications or treatments (e.g., steroids), or to toxin exposure. Similarly, the episode is not due to the direct physiological effects of a general medical condition (e.g., hypothyroidism) (Criterion D). Moreover, if the symptoms begin within 2 months of the loss of a loved one and do not persist beyond these 2 months, they are generally considered to result from Bereavement (see p. 740), unless they are associated with marked functional impairment or include morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation (Criterion E).

## Associated Features and Disorders

**Associated descriptive features and mental disorders.** Individuals with a Major Depressive Episode frequently present with tearfulness, irritability, brooding, obsessive rumination, anxiety, phobias, excessive worry over physical health, and complaints of pain (e.g., headaches or joint, abdominal, or other pains). During a Major Depressive Episode, some individuals have Panic Attacks that occur in a pattern that meets criteria for Panic Disorder. In children, separation anxiety may occur. Some individuals note difficulty in intimate relationships, less satisfying social interactions, or difficulties in sexual functioning (e.g., anorgasmia in women or erectile dysfunction in men). There may be marital problems (e.g., divorce), occupational problems (e.g., loss of job), academic problems (e.g., truancy, school failure), Alcohol or Other Substance Abuse, or increased utilization of medical services. The most serious consequence of a Major Depressive Episode is attempted or completed suicide. Suicide risk is especially high for individuals with psychotic features, a history of previous suicide attempts, a family history of completed suicides, or concurrent substance use. There may also be an increased rate of premature death from general medical conditions. Major Depressive Episodes often follow psychosocial stressors (e.g., the death of a loved one, marital separation, divorce). Childbirth may precipitate a Major Depressive Episode, in which case the specifier With Postpartum Onset is noted (see p. 422).

**Associated laboratory findings.** No laboratory findings that are diagnostic of a Major Depressive Episode have been identified. However, a variety of laboratory findings have been noted to be abnormal more often in groups of individuals with Major Depressive Episodes compared with control subjects. It appears that the same laboratory abnormalities are associated with a Major Depressive Episode regardless of whether the episode is part of a Major Depressive, Bipolar I, or Bipolar II Disorder. Most laboratory abnormalities are state dependent (i.e., affected by the presence or absence of depressive symptoms), but some findings may precede the onset of the episode or persist after its remission. Laboratory tests are more likely to be abnormal in episodes with melancholic or psychotic features and in more severely depressed individuals.

Sleep EEG abnormalities may be evident in 40%–60% of outpatients and in up to 90% of inpatients with a Major Depressive Episode. The most frequently associated polysomnographic findings include 1) sleep continuity disturbances, such as pro-

longed sleep latency, increased intermittent wakefulness, and early morning awakening; 2) reduced non–rapid eye movement (NREM) stages 3 and 4 sleep (slow-wave sleep), with a shift in slow-wave activity away from the first NREM period; 3) decreased rapid eye movement (REM) latency (i.e., shortened duration of the first NREM period); 4) increased phasic REM activity (i.e., the number of actual eye movements during REM); and 5) increased duration of REM sleep early in the night. There is evidence that these sleep abnormalities may persist after clinical remission or precede the onset of the initial Major Depressive Episode among those at high risk for a Mood Disorder (e.g., first-degree family members of individuals with Major Depressive Disorder).

The pathophysiology of a Major Depressive Episode may involve a dysregulation of a number of neurotransmitter systems, including the serotonin, norepinephrine, dopamine, acetylcholine, and gamma-aminobutyric acid systems. There is also evidence of alterations of several neuropeptides, including corticotropin-releasing hormone. In some depressed individuals, hormonal disturbances have been observed, including elevated glucocorticoid secretion (e.g., elevated urinary free cortisol levels or dexamethasone nonsuppression of plasma cortisol) and blunted growth hormone, thyroid-stimulating hormone, and prolactin responses to various challenge tests. Functional brain imaging studies document alterations in cerebral blood flow and metabolism in some individuals, including increased blood flow in limbic and paralimbic regions and decreased blood flow in the lateral prefrontal cortex. Depression beginning in late life is associated with alterations in brain structure, including periventricular vascular changes. None of these changes are present in all individuals in a Major Depressive Episode, however, nor is any particular disturbance specific to depression.

## Specific Culture, Age, and Gender Features

Culture can influence the experience and communication of symptoms of depression. Underdiagnosis or misdiagnosis can be reduced by being alert to ethnic and cultural specificity in the presenting complaints of a Major Depressive Episode. For example, in some cultures, depression may be experienced largely in somatic terms, rather than with sadness or guilt. Complaints of "nerves" and headaches (in Latino and Mediterranean cultures), of weakness, tiredness, or "imbalance" (in Chinese and Asian cultures), of problems of the "heart" (in Middle Eastern cultures), or of being "heartbroken" (among Hopi) may express the depressive experience. Such presentations combine features of the Depressive, Anxiety, and Somatoform Disorders. Cultures also may differ in judgments about the seriousness of experiencing or expressing dysphoria (e.g., irritability may provoke greater concern than sadness or withdrawal). Culturally distinctive experiences (e.g., fear of being hexed or bewitched, feelings of "heat in the head" or crawling sensations of worms or ants, or vivid feelings of being visited by those who have died) must be distinguished from actual hallucinations or delusions that may be part of a Major Depressive Episode, With Psychotic Features. It is also imperative that the clinician not routinely dismiss a symptom merely because it is viewed as the "norm" for a culture.

The core symptoms of a Major Depressive Episode are the same for children and adolescents, although there are data that suggest that the prominence of characteristic

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symptoms may change with age. Certain symptoms such as somatic complaints, irritability, and social withdrawal are particularly common in children, whereas psychomotor retardation, hypersomnia, and delusions are less common in prepuberty than in adolescence and adulthood. In prepubertal children, Major Depressive Episodes occur more frequently in conjunction with other mental disorders (especially Disruptive Behavior Disorders, Attention-Deficit Disorders, and Anxiety Disorders) than in isolation. In adolescents, Major Depressive Episodes are frequently associated with Disruptive Behavior Disorders, Attention-Deficit Disorders, Anxiety Disorders, Substance-Related Disorders, and Eating Disorders. In elderly adults, cognitive symptoms (e.g., disorientation, memory loss, and distractibility) may be particularly prominent.

Women are at significantly greater risk than men to develop Major Depressive Episodes at some point during their lives, with the greatest differences found in studies conducted in the United States and Europe. This increased differential risk emerges during adolescence and may coincide with the onset of puberty. Thereafter, a significant proportion of women report a worsening of the symptoms of a Major Depressive Episode several days before the onset of menses. Studies indicate that depressive episodes occur twice as frequently in women as in men. See the corresponding sections of the texts for Major Depressive Disorder (p. 372), Bipolar I Disorder (p. 385), and Bipolar II Disorder (p. 394) for specific information on gender.

## Course

Symptoms of a Major Depressive Episode usually develop over days to weeks. A prodromal period that may include anxiety symptoms and mild depressive symptoms may last for weeks to months before the onset of a full Major Depressive Episode. The duration of a Major Depressive Episode is also variable. An untreated episode typically lasts 4 months or longer, regardless of age at onset. In a majority of cases, there is complete remission of symptoms, and functioning returns to the premorbid level. In a significant proportion of cases (perhaps 20%–30%), some depressive symptoms insufficient to meet full criteria for a Major Depressive Episode may persist for months to years and may be associated with some disability or distress (in which case the specifier In Partial Remission may be noted; p. 412). Partial remission following a Major Depressive Episode appears to be predictive of a similar pattern after subsequent episodes. In some individuals (5%–10%), the full criteria for a Major Depressive Episode continue to be met for 2 or more years (in which case the specifier Chronic may be noted; see p. 417).

## Differential Diagnosis

A Major Depressive Episode must be distinguished from a **Mood Disorder Due to a General Medical Condition.** The appropriate diagnosis would be Mood Disorder Due to a General Medical Condition if the mood disturbance is judged to be the direct physiological consequence of a specific general medical condition (e.g., multiple sclerosis, stroke, hypothyroidism) (see p. 401). This determination is based on the history, laboratory findings, or physical examination. If both a Major Depressive Episode and a general medical condition are present but it is judged that the depressive symptoms

are not the direct physiological consequence of the general medical condition, then the primary Mood Disorder is recorded on Axis I (e.g., Major Depressive Disorder) and the general medical condition is recorded on Axis III (e.g., myocardial infarction). This would be the case, for example, if the Major Depressive Episode is considered to be the psychological consequence of having the general medical condition or if there is no etiological relationship between the Major Depressive Episode and the general medical condition.

A **Substance-Induced Mood Disorder** is distinguished from a Major Depressive Episode by the fact that a substance (e.g., a drug of abuse, a medication, or a toxin) is judged to be etiologically related to the mood disturbance (see p. 405). For example, depressed mood that occurs only in the context of withdrawal from cocaine would be diagnosed as Cocaine-Induced Mood Disorder, With Depressive Features, With Onset During Withdrawal.

In elderly persons, it is often difficult to determine whether cognitive symptoms (e.g., disorientation, apathy, difficulty concentrating, memory loss) are better accounted for by a **dementia** or by a Major Depressive Episode. A thorough medical evaluation and an evaluation of the onset of the disturbance, temporal sequencing of depressive and cognitive symptoms, course of illness, and treatment response are helpful in making this determination. The premorbid state of the individual may help to differentiate a Major Depressive Episode from a dementia. In a dementia, there is usually a premorbid history of declining cognitive function, whereas the individual with a Major Depressive Episode is much more likely to have a relatively normal premorbid state and abrupt cognitive decline associated with the depression.

Major Depressive Episodes with prominent irritable mood may be difficult to distinguish from **Manic Episodes with irritable mood** or from **Mixed Episodes.** This distinction requires a careful clinical evaluation of the presence of manic symptoms. If criteria are met for both a Manic Episode and a Major Depressive Episode (except for the 2-week duration) nearly every day for at least a 1-week period, this would constitute a Mixed Episode.

Distractibility and low frustration tolerance can occur in both **Attention-Deficit/Hyperactivity Disorder** and a Major Depressive Episode; if the criteria are met for both, Attention-Deficit/Hyperactivity Disorder may be diagnosed in addition to the Mood Disorder. However, the clinician must be cautious not to overdiagnose a Major Depressive Episode in children with Attention-Deficit/Hyperactivity Disorder whose disturbance in mood is characterized by irritability rather than by sadness or loss of interest.

A Major Depressive Episode that occurs in response to a psychosocial stressor is distinguished from **Adjustment Disorder With Depressed Mood** by the fact that the full criteria for a Major Depressive Episode are not met in Adjustment Disorder. After the loss of a loved one, even if depressive symptoms are of sufficient duration and number to meet criteria for a Major Depressive Episode, they should be attributed to **Bereavement** rather than to a Major Depressive Episode, unless they persist for more than 2 months or include marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.

Finally, periods of sadness are inherent aspects of the human experience. These periods should not be diagnosed as a Major Depressive Episode unless criteria are met for severity (i.e., five out of nine symptoms), duration (i.e., most of the day, nearly

every day for at least 2 weeks), and clinically significant distress or impairment. The diagnosis **Depressive Disorder Not Otherwise Specified** may be appropriate for presentations of depressed mood with clinically significant impairment that do not meet criteria for duration or severity.

## Criteria for Major Depressive Episode

A. Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure.

**Note:** Do not include symptoms that are clearly due to a general medical condition, or mood-incongruent delusions or hallucinations.

(1) depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful). **Note:** In children and adolescents, can be irritable mood.
(2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others)
(3) significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day. **Note:** In children, consider failure to make expected weight gains.
(4) insomnia or hypersomnia nearly every day
(5) psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
(6) fatigue or loss of energy nearly every day
(7) feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
(8) diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)
(9) recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

B. The symptoms do not meet criteria for a Mixed Episode (see p. 365).

C. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).

E. The symptoms are not better accounted for by Bereavement, i.e., after the loss of a loved one, the symptoms persist for longer than 2 months or are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.

# DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS

FOURTH EDITION

TEXT REVISION

# DSM-IV-TR®

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# EXHIBIT C2

Exhibit C2

# Impulse-Control Disorders Not Elsewhere Classified

This section includes disorders of impulse control that are not classified as part of the presentation of disorders in other sections of the manual (e.g., Substance-Related Disorders, Paraphilias, Antisocial Personality Disorder, Conduct Disorder, Schizophrenia, and Mood Disorders may have features that involve problems of impulse control). The essential feature of Impulse-Control Disorders is the failure to resist an impulse, drive, or temptation to perform an act that is harmful to the person or to others. For most of the disorders in this section, the individual feels an increasing sense of tension or arousal before committing the act and then experiences pleasure, gratification, or relief at the time of committing the act. Following the act there may or may not be regret, self-reproach, or guilt. The following disorders are included in this section:

**Intermittent Explosive Disorder** is characterized by discrete episodes of failure to resist aggressive impulses resulting in serious assaults or destruction of property.

**Kleptomania** is characterized by the recurrent failure to resist impulses to steal objects not needed for personal use or monetary value.

**Pyromania** is characterized by a pattern of fire setting for pleasure, gratification, or relief of tension.

**Pathological Gambling** is characterized by recurrent and persistent maladaptive gambling behavior.

**Trichotillomania** is characterized by recurrent pulling out of one's hair for pleasure, gratification, or relief of tension that results in noticeable hair loss.

**Impulse-Control Disorder Not Otherwise Specified** is included for coding disorders of impulse control that do not meet the criteria for any of the specific Impulse-Control Disorders described above or in other sections of the manual.

## 312.34 Intermittent Explosive Disorder

### Diagnostic Features

The essential feature of Intermittent Explosive Disorder is the occurrence of discrete episodes of failure to resist aggressive impulses that result in serious assaultive acts or destruction of property (Criterion A). Examples of serious assaultive acts include striking or otherwise hurting another person or verbally threatening to physically assault another individual. Destruction of property entails purposeful breaking of an object of value; minor or unintentional damage is not of sufficient severity to meet this criterion. The degree of aggressiveness expressed during an episode is grossly

out of proportion to any provocation or precipitating psychosocial stressor (Criterion B). A diagnosis of Intermittent Explosive Disorder is made only after other mental disorders that might account for episodes of aggressive behavior have been ruled out (e.g., Antisocial Personality Disorder, Borderline Personality Disorder, a Psychotic Disorder, a Manic Episode, Conduct Disorder, or Attention-Deficit/Hyperactivity Disorder) (Criterion C). The aggressive episodes are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., head trauma, Alzheimer's disease) (Criterion C). The individual may describe the aggressive episodes as "spells" or "attacks" in which the explosive behavior is preceded by a sense of tension or arousal and is followed immediately by a sense of relief. Later the individual may feel upset, remorseful, regretful, or embarrassed about the aggressive behavior.

## Associated Features and Disorders

**Associated descriptive features and mental disorders.** Individuals with Intermittent Explosive Disorder sometimes describe intense impulses to be aggressive prior to their aggressive acts. Explosive episodes may be associated with affective symptoms (irritability or rage, increased energy, racing thoughts) during the aggressive impulses and acts, and rapid onset of depressed mood and fatigue after the acts. Some individuals may also report that their aggressive episodes are often preceded or accompanied by symptoms such as tingling, tremor, palpitations, chest tightness, head pressure, or hearing an echo. Individuals may describe their aggressive impulses as extremely distressing. The disorder may result in job loss, school suspension, divorce, difficulties with interpersonal relationships or other impairment in social or occupational spheres, accidents (e.g., in vehicles), hospitalization (e.g., because of injuries incurred in fights or accidents), financial problems, incarcerations, or other legal problems.

Signs of generalized impulsivity or aggressiveness may be present between explosive episodes. Individuals with Intermittent Explosive Disorder may report problems with chronic anger and frequent "subthreshold" episodes, in which they experience aggressive impulses but either manage to resist acting on them or engage in less destructive aggressive behaviors (e.g., screaming, punching a wall without damaging it).

Individuals with narcissistic, obsessive, paranoid, or schizoid traits may be especially prone to having explosive outbursts of anger when under stress. Preliminary data suggest that Mood Disorders, Anxiety Disorders, Eating Disorders, Substance Use Disorders, and other Impulse-Control Disorders may be associated with Intermittent Explosive Disorder. Childhood histories may show severe temper tantrums, impaired attention, hyperactivity, and other behavioral difficulties, such as stealing and fire setting.

**Associated laboratory findings.** There may be nonspecific EEG findings (e.g., slowing) or evidence of abnormalities on neuropsychological testing (e.g., difficulty with letter reversal). Signs of altered serotonin metabolism (e.g., low mean 5-hydroxyindoleacetic acid [5-HIAA] concentrations) have been found in the cerebrospinal fluid of some impulsive and temper-prone individuals, but the specific relationship of these findings to Intermittent Explosive Disorder is unclear.

**Associated physical examination findings and general medical conditions.** There may be nonspecific or "soft" findings on neurological examinations (e.g., reflex asymmetries or mirror movements). Developmental difficulties indicative of cerebral dysfunction may be present (e.g., delayed speech or poor coordination). A history of neurological conditions (e.g., migraine headaches, head injury, episodes of unconsciousness, or febrile seizures in childhood) may be present. However, if the clinician judges that the aggressive behavior is a consequence of the direct physiological effects of a diagnosable general medical condition, the appropriate Mental Disorder Due to a General Medical Condition should be diagnosed instead (e.g., Personality Change Due to Head Trauma, Aggressive Type; Dementia of the Alzheimer's Type, Early Onset, Uncomplicated, With Behavioral Disturbance).

## Specific Culture and Gender Features

*Amok* is characterized by an episode of acute, unrestrained violent behavior for which the person claims amnesia. Although traditionally seen in southeastern Asian countries, cases of amok have been reported in Canada and the United States. Unlike Intermittent Explosive Disorder, amok typically occurs as a single episode rather than as a pattern of aggressive behavior and is often associated with prominent dissociative features. Episodic violent behavior is more common in males than in females.

## Prevalence

Reliable information is lacking, but Intermittent Explosive Disorder is apparently rare.

## Course

Limited data are available on the age at onset of Intermittent Explosive Disorder, but it appears to be from childhood to the early 20s. Mode of onset may be abrupt and without a prodromal period. The course of Intermittent Explosive Disorder is variable, with the disorder having a chronic course in some individuals and a more episodic course in other individuals.

## Familial Pattern

Mood Disorders, Substance Use Disorders, Intermittent Explosive Disorder, and other Impulse-Control Disorders may be more common among the first-degree relatives of individuals with Intermittent Explosive Disorder than among the general population.

## Differential Diagnosis

Aggressive behavior can occur in the context of many other mental disorders. A diagnosis of Intermittent Explosive Disorder should be considered only after all other disorders that are associated with aggressive impulses or behavior have been ruled out. If the aggressive behavior occurs exclusively during the course of a delirium, a

diagnosis of Intermittent Explosive Disorder is not given. Similarly, when the behavior develops as part of a **dementia**, a diagnosis of Intermittent Explosive Disorder is not made and the appropriate diagnosis is dementia with the specifier With Behavioral Disturbance. Intermittent Explosive Disorder should be distinguished from **Personality Change Due to a General Medical Condition, Aggressive Type**, which is diagnosed when the pattern of aggressive episodes is judged to be due to the direct physiological effects of a diagnosable general medical condition (e.g., an individual who has suffered brain injury from an automobile accident and subsequently manifests a change in personality characterized by aggressive outbursts). In rare cases, episodic violence may occur in individuals with epilepsy, especially of frontal and temporal origin (partial complex epilepsy).

A careful history and a thorough neurological evaluation are helpful in making the determination. Note that nonspecific abnormalities on neurological examination (e.g., "soft signs") and nonspecific EEG changes are compatible with a diagnosis of Intermittent Explosive Disorder and only preempt the diagnosis if they are indicative of a diagnosable general medical condition.

Aggressive outbursts may also occur in association with **Substance Intoxication** or **Substance Withdrawal**, particularly associated with alcohol, phencyclidine, cocaine and other stimulants, barbiturates, and inhalants. The clinician should inquire carefully about the nature and extent of substance use, and a blood or urine drug screen may be informative.

Intermittent Explosive Disorder should be distinguished from the aggressive or erratic behavior that can occur in **Oppositional Defiant Disorder, Conduct Disorder, Antisocial Personality Disorder, Borderline Personality Disorder**, a **Manic Episode**, and **Schizophrenia**. If the aggressive behavior is better accounted for as a diagnostic or associated feature of another mental disorder, a separate diagnosis of Intermittent Explosive Disorder is not given. However, impulsive aggression in individuals with Antisocial Personality Disorder and Borderline Personality Disorder can have specific clinical relevance, in which case both diagnoses may be made. For example, if an individual with an established diagnosis of Borderline Personality Disorder develops discrete episodes of failure to resist aggressive impulses resulting in serious physical or verbal assaultive acts or destruction of property, an additional diagnosis of Intermittent Explosive Disorder may be warranted.

"**Anger attacks**"—sudden spells of anger associated with autonomic arousal (tachycardia, sweating, flushing) and feelings of being out of control—have been described in individuals with **Major Depressive Disorder** and **Panic Disorder**. If these attacks occur only in the setting of a Major Depressive Episode or a Panic Attack, they should not count toward a diagnosis of Intermittent Explosive Disorder. However, if these anger attacks also occur at times other than during Major Depressive Episodes or Panic Attacks, and meet the Intermittent Explosive Disorder criterion for serious assaultive acts, then both diagnoses may be given.

Aggressive behavior may, of course, occur when no mental disorder is present. **Purposeful behavior** is distinguished from Intermittent Explosive Disorder by the presence of motivation and gain in the aggressive act. In forensic settings, individuals may **malinger** Intermittent Explosive Disorder to avoid responsibility for their behavior. **Anger as a normal reaction to specific life events or environmental situations** also needs to be distinguished from the anger that may occur as part of an

aggressive episode in Intermittent Explosive Disorder, which occurs with little or no provocation.

**Diagnostic criteria for 312.34 Intermittent Explosive Disorder**

A. Several discrete episodes of failure to resist aggressive impulses that result in serious assaultive acts or destruction of property.

B. The degree of aggressiveness expressed during the episodes is grossly out of proportion to any precipitating psychosocial stressors.

C. The aggressive episodes are not better accounted for by another mental disorder (e.g., Antisocial Personality Disorder, Borderline Personality Disorder, a Psychotic Disorder, a Manic Episode, Conduct Disorder, or Attention-Deficit/Hyperactivity Disorder) and are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., head trauma, Alzheimer's disease).

## 312.32 Kleptomania

### Diagnostic Features

The essential feature of Kleptomania is the recurrent failure to resist impulses to steal items even though the items are not needed for personal use or for their monetary value (Criterion A). The individual experiences a rising subjective sense of tension before the theft (Criterion B) and feels pleasure, gratification, or relief when committing the theft (Criterion C). The stealing is not committed to express anger or vengeance, is not done in response to a delusion or hallucination (Criterion D), and is not better accounted for by Conduct Disorder, a Manic Episode, or Antisocial Personality Disorder (Criterion E). The objects are stolen despite the fact that they are typically of little value to the individual, who could have afforded to pay for them and often gives them away or discards them. Occasionally the individual may hoard the stolen objects or surreptitiously return them. Although individuals with this disorder will generally avoid stealing when immediate arrest is probable (e.g., in full view of a police officer), they usually do not preplan the thefts or fully take into account the chances of apprehension. The stealing is done without assistance from, or collaboration with, others.

### Associated Features and Disorders

Individuals with Kleptomania experience the impulse to steal as ego-dystonic and are aware that the act is wrong and senseless. The person frequently fears being apprehended and often feels depressed or guilty about the thefts. Kleptomania may be associated with compulsive buying as well as with Mood Disorders (especially Major Depressive Disorder), Anxiety Disorders, Eating Disorders (particularly Bulimia

Nervosa), Personality Disorders, and other Impulse-Control Disorders. The disorder may cause legal, family, career, and personal difficulties.

## Specific Gender Features

Preliminary evidence suggests that, in clinical samples, approximately two-thirds of individuals with Kleptomania are female.

## Prevalence

Kleptomania is a rare condition that appears to occur in fewer than 5% of identified shoplifters. Its prevalence in the general population is unknown.

## Course

Age at onset of Kleptomania is variable. The disorder may begin in childhood, adolescence, or adulthood, and in rare cases in late adulthood. There is little systematic information on the course of Kleptomania, but three typical courses have been described: sporadic with brief episodes and long periods of remission; episodic with protracted periods of stealing and periods of remission; and chronic with some degree of fluctuation. The disorder may continue for years, despite multiple convictions for shoplifting.

## Familial Pattern

There are no controlled family history studies of Kleptomania. However, preliminary data suggest that first-degree relatives of individuals with Kleptomania may have higher rates of Obsessive-Compulsive Disorder than the general population.

## Differential Diagnosis

Kleptomania should be distinguished from **ordinary acts of theft or shoplifting.** Ordinary theft (whether planned or impulsive) is deliberate and is motivated by the usefulness of the object or its monetary worth. Some individuals, especially adolescents, may also steal on a dare, as an act of rebellion, or as a rite of passage. The diagnosis is not made unless other characteristic features of Kleptomania are also present. Kleptomania is exceedingly rare, whereas shoplifting is relatively common. In **Malingering,** individuals may simulate the symptoms of Kleptomania to avoid criminal prosecution. **Antisocial Personality Disorder** and **Conduct Disorder** are distinguished from Kleptomania by a general pattern of antisocial behavior. Kleptomania should be distinguished from intentional or inadvertent stealing that may occur during a **Manic Episode,** in response to delusions or hallucinations (e.g., in **Schizophrenia**), or as a result of a **dementia.**



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## Diagnostic criteria for 312.32 Kleptomania

A. Recurrent failure to resist impulses to steal objects that are not needed for personal use or for their monetary value.

B. Increasing sense of tension immediately before committing the theft.

C. Pleasure, gratification, or relief at the time of committing the theft.

D. The stealing is not committed to express anger or vengeance and is not in response to a delusion or a hallucination.

E. The stealing is not better accounted for by Conduct Disorder, a Manic Episode, or Antisocial Personality Disorder.

# 312.33 Pyromania

## Diagnostic Features

The essential feature of Pyromania is the presence of multiple episodes of deliberate and purposeful fire setting (Criterion A). Individuals with this disorder experience tension or affective arousal before setting a fire (Criterion B). There is a fascination with, interest in, curiosity about, or attraction to fire and its situational contexts (e.g., paraphernalia, uses, consequences) (Criterion C). Individuals with this disorder are often regular "watchers" at fires in their neighborhoods, may set off false alarms, and derive pleasure from institutions, equipment, and personnel associated with fire. They may spend time at the local fire department, set fires to be affiliated with the fire department, or even become firefighters. Individuals with this disorder experience pleasure, gratification, or a release of tension when setting the fire, witnessing its effects, or participating in its aftermath (Criterion D). The fire setting is not done for monetary gain, as an expression of sociopolitical ideology, to conceal criminal activity, to express anger or vengeance, to improve one's living circumstances, or in response to a delusion or a hallucination (Criterion E). The fire setting does not result from impaired judgment (e.g., in dementia or Mental Retardation). The diagnosis is not made if the fire setting is better accounted for by Conduct Disorder, a Manic Episode, or Antisocial Personality Disorder (Criterion F).

## Associated Features and Disorders

Individuals with Pyromania may make considerable advance preparation for starting a fire. They may be indifferent to the consequences to life or property caused by the fire, or they may derive satisfaction from the resulting property destruction. The behaviors may lead to property damage, legal consequences, or injury or loss of life to the fire setter or to others. Individuals who impulsively set fires (who may or may not have Pyromania) often have a current or past history of Alcohol Dependence or Abuse.

## Specific Age and Gender Features

Although fire setting is a major problem in children and adolescents (over 40% of those arrested for arson offenses in the United States are under age 18 years), Pyromania in childhood appears to be rare. Juvenile fire setting is usually associated with Conduct Disorder, Attention-Deficit/Hyperactivity Disorder, or Adjustment Disorder. Pyromania occurs much more often in males, especially those with poorer social skills and learning difficulties.

## Prevalence

Pyromania is apparently rare.

## Course

There are insufficient data to establish a typical age at onset of Pyromania. The relationship between fire setting in childhood and Pyromania in adulthood has not been documented. In individuals with Pyromania, fire-setting incidents are episodic and may wax and wane in frequency. Longitudinal course is unknown.

## Differential Diagnosis

It is important to rule out other causes of fire setting before giving the diagnosis of Pyromania. Intentional fire setting may occur for **profit, sabotage, or revenge; to conceal a crime; to make a political statement** (e.g., an act of terrorism or protest); or to **attract attention or recognition** (e.g., setting a fire in order to discover it and save the day). Fire setting may also occur as part of **developmental experimentation in childhood** (e.g., playing with matches, lighters, or fire). Some individuals with mental disorders use fire setting to communicate a desire, wish, or need, often directed at gaining a change in the nature or location of services. This form of fire setting has been referred to as "communicative arson" and must be carefully distinguished from Pyromania. A separate diagnosis of Pyromania is not given when fire setting occurs as part of **Conduct Disorder**, a **Manic Episode**, or **Antisocial Personality Disorder**, or if it occurs in response to a delusion or a hallucination (e.g., in **Schizophrenia**) or if it is due to the direct physiological effects of a general medical condition (e.g., epilepsy). The diagnosis of Pyromania should also not be given when fire setting results from impaired judgment associated with **dementia, Mental Retardation**, or **Substance Intoxication**.



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## Diagnostic criteria for 312.33 Pyromania

A. Deliberate and purposeful fire setting on more than one occasion.

B. Tension or affective arousal before the act.

C. Fascination with, interest in, curiosity about, or attraction to fire and its situational contexts (e.g., paraphernalia, uses, consequences).

D. Pleasure, gratification, or relief when setting fires, or when witnessing or participating in their aftermath.

E. The fire setting is not done for monetary gain, as an expression of sociopolitical ideology, to conceal criminal activity, to express anger or vengeance, to improve one's living circumstances, in response to a delusion or hallucination, or as a result of impaired judgment (e.g., in dementia, Mental Retardation, Substance Intoxication).

F. The fire setting is not better accounted for by Conduct Disorder, a Manic Episode, or Antisocial Personality Disorder.

# 312.31 Pathological Gambling

## Diagnostic Features

The essential feature of Pathological Gambling is persistent and recurrent maladaptive gambling behavior (Criterion A) that disrupts personal, family, or vocational pursuits. The diagnosis is not made if the gambling behavior is better accounted for by a Manic Episode (Criterion B).

The individual may be preoccupied with gambling (e.g., reliving past gambling experiences, planning the next gambling venture, or thinking of ways to get money with which to gamble) (Criterion A1). Most individuals with Pathological Gambling say that they are seeking "action" (an aroused, euphoric state) or excitement even more than money. Increasingly larger bets, or greater risks, may be needed to continue to produce the desired level of excitement (Criterion A2). Individuals with Pathological Gambling often continue to gamble despite repeated efforts to control, cut back, or stop the behavior (Criterion A3). There may be restlessness or irritability when attempting to cut down or stop gambling (Criterion A4). The individual may gamble as a way of escaping from problems or to relieve a dysphoric mood (e.g., feelings of helplessness, guilt, anxiety, depression) (Criterion A5). A pattern of "chasing" one's losses may develop, with an urgent need to keep gambling (often with larger bets or the taking of greater risks) to undo a loss or series of losses. The individual may abandon his or her gambling strategy and try to win back losses all at once. Although all gamblers may chase for short periods, it is the long-term chase that is more characteristic of individuals with Pathological Gambling (Criterion A6). The individual may lie to family members, therapists, or others to conceal the extent of involvement with gambling (Criterion A7). When the individual's borrowing resources are

strained, the person may resort to antisocial behavior (e.g., forgery, fraud, theft, or embezzlement) to obtain money (Criterion A8). The individual may have jeopardized or lost a significant relationship, job, or educational or career opportunity because of gambling (Criterion A9). The individual may also engage in "bailout" behavior, turning to family or others for help with a desperate financial situation that was caused by gambling (Criterion A10).

## Associated Features and Disorders

**Associated descriptive features and mental disorders.** Distortions in thinking (e.g., denial, superstitions, overconfidence, or a sense of power and control) may be present in individuals with Pathological Gambling. Many individuals with Pathological Gambling believe that money is both the cause of and solution to all their problems. Individuals with Pathological Gambling are frequently highly competitive, energetic, restless, and easily bored. They may be overly concerned with the approval of others and may be generous to the point of extravagance. When not gambling, they may be workaholics or "binge" workers who wait until they are up against deadlines before really working hard. They may be prone to developing general medical conditions that are associated with stress (e.g., hypertension, peptic ulcer disease, migraine). Individuals seeking treatment for Pathological Gambling have relatively high rates of suicidal ideation and suicide attempts. Studies of men with Pathological Gambling suggest that a history of inattentive and hyperactive symptoms in childhood may be a risk factor for development of Pathological Gambling later in life. Increased rates of Mood Disorders, Attention-Deficit/Hyperactivity Disorder, Substance Abuse or Dependence, other Impulse-Control Disorders, and Antisocial, Narcissistic, and Borderline Personality Disorders have been reported in individuals with Pathological Gambling.

**Associated laboratory findings.** There are no laboratory findings that are diagnostic of Pathological Gambling. However, a variety of laboratory findings have been reported to be abnormal in males with Pathological Gambling compared with control subjects. These include measures of neurotransmitters and their metabolites in cerebrospinal fluid and urine, and response to neuroendocrine challenges, implicating abnormalities in a variety of neurotransmitter systems, including the serotonin, norepinephrine, and dopamine systems. Abnormalities in platelet monoamine oxidase activity have also been reported in males with Pathological Gambling. Individuals with Pathological Gambling may display high levels of impulsivity on neuropsychological tests.

## Specific Culture and Gender Features

There are cultural variations in the prevalence and type of gambling activities (e.g., pai go, cockfights, horse racing, the stock market). Approximately one-third of individuals with Pathological Gambling are females, but in different geographic areas and cultures, gender ratio can vary considerably. Females with the disorder are more apt to be depressed and to gamble as an escape. Females are underrepresented in treatment programs for gambling and represent only 2%–4% of the population of

Gamblers Anonymous. This may be a function of the greater stigma attached to female gamblers.

## Prevalence

The prevalence of Pathological Gambling is influenced by both the availability of gambling and the duration of availability such that with the increasing availability of legalized gambling, there is an increase in the prevalence of Pathological Gambling. Community studies estimate the lifetime prevalence of Pathological Gambling to range from 0.4% to 3.4% in adults, although prevalence rates in some areas (e.g., Puerto Rico, Australia) have been reported to be as high as 7%. Higher prevalence rates, ranging from 2.8% to 8%, have been reported in adolescents and college students. The prevalence of Pathological Gambling may be increased in treatment-seeking individuals with a Substance Use Disorder.

## Course

Pathological Gambling typically begins in early adolescence in males and later in life in females. Although a few individuals are "hooked" with their very first bet, for most the course is more insidious. There may be years of social gambling followed by an abrupt onset that may be precipitated by greater exposure to gambling or by a stressor. The gambling pattern may be regular or episodic, and the course of the disorder is typically chronic. There is generally a progression in the frequency of gambling, the amount wagered, and the preoccupation with gambling and obtaining money with which to gamble. The urge to gamble and gambling activity generally increase during periods of stress or depression.

## Familial Pattern

Pathological Gambling and Alcohol Dependence are both more common among the parents of individuals with Pathological Gambling than among the general population.

## Differential Diagnosis

Pathological Gambling must be distinguished from social gambling and professional gambling. **Social gambling** typically occurs with friends or colleagues and lasts for a limited period of time, with predetermined acceptable losses. In **professional gambling**, risks are limited and discipline is central. Some individuals can experience problems associated with their gambling (e.g., short-term chasing behavior and loss of control) that do not meet the full criteria for Pathological Gambling.

Loss of judgment and excessive gambling may occur during a **Manic Episode**. An additional diagnosis of Pathological Gambling should only be given if the gambling behavior is not better accounted for by the Manic Episode (e.g., a history of maladaptive gambling behavior at times other than during a Manic Episode). Alternatively, an individual with Pathological Gambling may exhibit behavior during a gambling binge that resembles a Manic Episode. However, once the individual is away from the

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gambling, these manic-like features dissipate. Problems with gambling may occur in individuals with **Antisocial Personality Disorder**; if criteria are met for both disorders, both can be diagnosed.

### Diagnostic criteria for 312.31 Pathological Gambling

A. Persistent and recurrent maladaptive gambling behavior as indicated by five (or more) of the following:

(1) is preoccupied with gambling (e.g., preoccupied with reliving past gambling experiences, handicapping or planning the next venture, or thinking of ways to get money with which to gamble)
(2) needs to gamble with increasing amounts of money in order to achieve the desired excitement
(3) has repeated unsuccessful efforts to control, cut back, or stop gambling
(4) is restless or irritable when attempting to cut down or stop gambling
(5) gambles as a way of escaping from problems or of relieving a dysphoric mood (e.g., feelings of helplessness, guilt, anxiety, depression)
(6) after losing money gambling, often returns another day to get even ("chasing" one's losses)
(7) lies to family members, therapist, or others to conceal the extent of involvement with gambling
(8) has committed illegal acts such as forgery, fraud, theft, or embezzlement to finance gambling
(9) has jeopardized or lost a significant relationship, job, or educational or career opportunity because of gambling
(10) relies on others to provide money to relieve a desperate financial situation caused by gambling

B. The gambling behavior is not better accounted for by a Manic Episode.

## 312.39 Trichotillomania

### Diagnostic Features

The essential feature of Trichotillomania is the recurrent pulling out of one's own hair that results in noticeable hair loss (Criterion A). Sites of hair pulling may include any region of the body in which hair may grow (including axillary, pubic, and perirectal regions), with the most common sites being the scalp, eyebrows, and eyelashes. Hair pulling may occur in brief episodes scattered throughout the day or in less frequent but more sustained periods that can continue for hours. Hair pulling often occurs in states of relaxation and distraction (e.g., when reading a book or watching television) but may also occur during stressful circumstances. An increasing sense of tension is present immediately before pulling out the hair (Criterion B). For some, tension does not necessarily precede the act but is associated with attempts to resist the urge. There is gratification, pleasure, or a sense of relief when pulling out the hair (Criterion C). Some

individuals experience an "itchlike" sensation in the scalp that is eased by the act of pulling hair. The diagnosis is not given if the hair pulling is better accounted for by another mental disorder (e.g., in response to a delusion or a hallucination) or is due to a general medical condition (e.g., inflammation of the skin or other dermatological conditions) (Criterion D). The disturbance must cause significant distress or impairment in social, occupational, or other important areas of functioning (Criterion E).

## Associated Features and Disorders

**Associated descriptive features and mental disorders.** Examining the hair root, twirling it off, pulling the strand between the teeth, or trichophagia (eating hairs) may occur with Trichotillomania. Hair pulling does not usually occur in the presence of other people (except immediate family members), and social situations may be avoided. Individuals commonly deny their hair-pulling behavior and conceal or camouflage the resulting alopecia. Some individuals have urges to pull hairs from other people and may sometimes try to find opportunities to do so surreptitiously. They may pull hairs from pets, dolls, and other fibrous materials (e.g., sweaters or carpets). Nail biting, scratching, gnawing, and excoriation is often associated with Trichotillomania. Individuals with Trichotillomania may also have Mood Disorders, Anxiety Disorders (especially Obsessive-Compulsive Disorder), Substance Use Disorders, Eating Disorders, Personality Disorders, or Mental Retardation.

**Associated laboratory findings.** Certain histological findings are considered characteristic and may aid diagnosis when Trichotillomania is suspected and the affected individual denies symptoms. Biopsy samples from involved areas may reveal short and broken hairs. Histological examination will reveal normal and damaged follicles in the same area, as well as an increased number of catagen hairs. Some hair follicles may show signs of trauma (wrinkling of the outer root sheath). Involved follicles may be empty or may contain a deeply pigmented keratinous material. The absence of inflammation distinguishes Trichotillomania-induced alopecia from alopecia areata.

**Associated physical examination findings and general medical conditions.** Pain is not routinely reported to accompany the hair pulling; pruritus and tingling in the involved areas may be present. The patterns of hair loss are highly variable. Areas of complete alopecia are common, as well as areas of noticeably thinned hair density. When the scalp is involved, there may be a predilection for the crown or parietal regions. The surface of the scalp usually shows no evidence of excoriation. There may be a pattern of nearly complete baldness except for a narrow perimeter around the outer margins of the scalp, particularly at the nape of the neck ("tonsure trichotillomania"). Eyebrows and eyelashes may be completely absent. Thinning of pubic hairs may be apparent on inspection. There may be areas of absent hair on the limbs or torso. Trichophagia may result in bezoars (hair balls) that may lead to anemia, abdominal pain, hematemesis, nausea and vomiting, and bowel obstruction and even perforation.

## Specific Culture, Age, and Gender Features

Among children with Trichotillomania, males and females are equally represented. Among adults, Trichotillomania is much more common among females than among males. This may reflect the true gender ratio of the condition, or it may reflect differential treatment seeking based on cultural or gender-based attitudes regarding appearance (e.g., acceptance of normative hair loss among males).

## Prevalence

No systematic data are available on the prevalence of Trichotillomania. Although Trichotillomania was previously thought to be an uncommon condition, it is now believed to occur more frequently. For example, a survey of college students found a lifetime rate of 0.6%.

## Course

Transient periods of hair pulling in early childhood may be considered a benign "habit" with a self-limited course. Individuals who present with chronic Trichotillomania in adulthood often report onset in early adolescence. Some individuals have continuous symptoms for decades. For others, the disorder may come and go for weeks, months, or years at a time. Sites of hair pulling may vary over time.

## Differential Diagnosis

**Other causes of alopecia** should be considered in individuals who deny hair pulling (e.g., alopecia areata, male-pattern baldness, chronic discoid lupus erythematosus, lichen planopilaris, folliculitis decalvans, pseudopelade, and alopecia mucinosa). A separate diagnosis of Trichotillomania is not given if the behavior is better accounted for by **another mental disorder** (e.g., in response to a delusion or a hallucination in Schizophrenia). The repetitive hair pulling in Trichotillomania must be distinguished from a compulsion, as in **Obsessive-Compulsive Disorder.** In Obsessive-Compulsive Disorder, the repetitive behaviors are performed in response to an obsession, or according to rules that must be applied rigidly. An additional diagnosis of **Stereotypic Movement Disorder** is not made if the repetitive behavior is limited to hair pulling. The self-induced alopecia in Trichotillomania must be distinguished from **Factitious Disorder With Predominantly Physical Signs and Symptoms,** in which the motivation for the behavior is assuming the sick role.

Many individuals twist and play with hair, especially during states of heightened anxiety, but this behavior does not usually qualify for a diagnosis of Trichotillomania. Some individuals may present with features of Trichotillomania, but the resulting hair damage may be so slight as to be virtually undetectable. In such situations, the diagnosis should only be considered if the individual experiences significant distress. In children, self-limited periods of hair pulling are common and may be considered a temporary "habit." This form of childhood hair pulling differs from adult forms of Trichotillomania in that there may be an absence of reported tension or relief associated with the hair pulling. Therefore, among children, the diagnosis should be reserved for situations in which the behavior has persisted for several months.

### Diagnostic criteria for 312.39 Trichotillomania

A. Recurrent pulling out of one's hair resulting in noticeable hair loss.

B. An increasing sense of tension immediately before pulling out the hair or when attempting to resist the behavior.

C. Pleasure, gratification, or relief when pulling out the hair.

D. The disturbance is not better accounted for by another mental disorder and is not due to a general medical condition (e.g., a dermatological condition).

E. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

## 312.30 Impulse-Control Disorder Not Otherwise Specified

This category is for disorders of impulse control (e.g., skin picking) that do not meet the criteria for any specific Impulse-Control Disorder or for another mental disorder having features involving impulse control described elsewhere in the manual (e.g., Substance Dependence, a Paraphilia).

# DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS

FOURTH EDITION

TEXT REVISION

# DSM-IV-TR®

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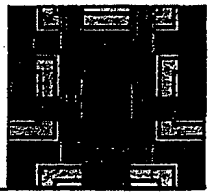
CHAPTER 31



# Impulse-Control Disorders Measures

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## INTRODUCTION

### Major Domains

This chapter covers tests and instruments that assess the DSM-IV category of impulse-control disorders, which is composed of the following diagnoses: intermittent explosive disorder, trichotillomania, pathological gambling, kleptomania, pyromania, and impulse-control disorder not otherwise specified. Also described are state and trait measures of anger, aggression, and impulsivity. At present there are no published tests specifically designed to measure most of the impulse-control disorders listed. Therefore, we include instruments for only two of the six diagnoses: a measure of pathological gambling (the South Oaks Gambling Screen [SOGS]) and two measures for trichotillomania (the Psychiatric Institute Trichotillomania Scale [PITS] and the Massachusetts General Hospital [MGH] Hairpulling Scale). The remaining five measures in this chapter assess general dimensions of anger, aggression, and impulsivity.

*Impulsivity* is generally defined as acting without thinking or as behaving recklessly without regard to consequences. Impulsivity as a dimension is measured by the Barratt Impulsiveness Scale, Version 11 (BIS-11). Anger, aggression, and hostility cover a range of constructs that encompass subjective emotional experience, quality of emotional reactivity, patterns of emotional expression, inhibition or disinhibition of anger responses, and associated verbal and physical behaviors. In this chapter we include four anger and aggression instruments that differ considerably in their focus: the Anger, Irritability, and Assault Questionnaire (AIAQ); the Buss-Durkee Hostility Inventory (BDHI); the Overt Aggression Scale—Modified (OAS-M); and the State-Trait Anger Expression Inventory (STAXI). The relationship between the constructs of impulsivity and aggression and specific impulse-control disorders is complex. Although these dimensional scales do not measure specific diagnostic entities, they are included because of their relevance to the constructs underlying the diagnostic category of impulse-control disorder. High trait levels of impulsivity and/or aggression may dispose people to perform the behaviors associated with specific impulse-control disorders, such as pathological gambling, intermittent explosive disorder, or impulse-control disorder not otherwise specified. For example, high scores on the Motor Impulsiveness factor of the BIS-11 have been associated with a greater number of impulsive acts in inmates.

### Organization

The measures included in this chapter are listed in Table 31–1. Because *impulsiveness* is a general concept that cuts across these disorders, the first measure presented is the BIS-11. We then describe four scales for assessing anger and aggression that may be relevant in the assessment of the DSM-IV category intermittent explosive disorder. Finally, we present the three scales that can be used to

TABLE 31–1 ■ Impulse-control disorders measures

| Name of measure | Disorder or construct assessed | Format | Pages |
|---|---|---|---|
| Barratt Impulsiveness Scale, Version 11 (BIS-11)* | Impulsivity | Self-administered questionnaire; 30 items | 691–693 |
| Anger, Irritability, and Assault Questionnaire (AIAQ)* | Impulsive aggression | Self-report; 84 items (original), 210 items (revised) | 694–697 |
| Buss-Durkee Hostility Inventory (BDHI)* | Components of hostility | Self-report; 75 items | 697–699 |
| Overt Aggression Scale—Modified (OAS-M)* | Aggressive behavior in outpatients | Semistructured interview; 25 items | 699–702 |
| State-Trait Anger Expression Inventory (STAXI) | Components of anger | Self-administered questionnaire; 44 items | 702–706 |
| South Oaks Gambling Screen (SOGS)* | Pathological gambling | Interview or self-report; 20 items | 706–708 |
| Massachusetts General Hospital (MGH) Hairpulling Scale* | Trichotillomania | Self-report questionnaire; 7 items | 708–710 |
| Psychiatric Institute Trichotillomania Scale (PITS)* | Trichotillomania | Semistructured interview; 6 items | 711–712 |

*Measure is included on the CD-ROM that accompanies this handbook.

assess specific DSM diagnoses, one for pathological gambling and two for trichotillomania.

### Relevant Measures Included Elsewhere in the Handbook

With the exception of the OAS-M, measures of autoaggressive or self-mutilative behavior are found in Chapter 16, "Suicide Risk Measures." Measures that primarily assess children's and adolescents' behavior are found in Chapter 17, "Child and Adolescent Measures for Diagnosis and Screening," Chapter 18, "Symptom-Specific Measures for Disorders Usually First Diagnosed in Infancy, Childhood, or Adolescence," and Chapter 19, "Child and Adolescent Measures of Functional Status."

## USING MEASURES IN THIS DOMAIN

### Goals of Assessment

The main goals of assessment within this domain are measuring current, recent, and remote episodes of violent or aggressive behavior; determining the severity of current anger, aggression, hostility, hair pulling, or gambling; and measuring change over time. Assessment is intended to aid in determining the patient's propensity toward impulsivity, anger, or hostility as a personality trait and thus whether a patient meets the criteria for a particular impulse-control disorder. Such information can be of use in clinical evaluation, treatment planning, and evaluation of response to treatment. All of the measures are appropriate for use in research as well.

### Implementation Issues

Six of the eight measures are self-report questionnaires, although one (the SOGS) can also be administered as a semistructured interview. Two measures (the PITS and the OAS-M) are semistructured interviews.

Measures also have varying time frames; they can assess current state (e.g., the STAXI), state or trait across the past week (e.g., the AIAQ, the OAS-M, the MGH Hairpulling Scale, and the PITS), or trait across lifetime (e.g., the STAXI, the AIAQ, and the SOGS). The AIAQ offers three time frames in the initial version and five time frames in a later revision. Neither the BDHI nor the BIS-11 specifies a time frame.

Many of the measures included in this chapter have common limitations. First, all the dimensional measures assess traits that are generally considered socially undesirable and are thus sensitive to social desirability biases, because subjects may be tempted to underreport undesirable traits. Moreover, most of the dimensional instruments are self-report measures, which are vulnerable to several reporting biases. Findings may be confounded by subjects' poor insight into their own attitudes and behaviors, by desires to portray themselves favorably or to exaggerate their impairment and distress in an attempt to affect treatment, and by subjects' misunderstanding of the questions or instructions.

In addition, most self-report scales are aimed at subjects of normal intellect. Thus, many scales may not be appropriate for intellectually impaired subjects. Although none of the scales in this chapter are specifically designed for nonverbal or intellectually impaired subjects, those that focus primarily on assessment of concrete behavior, such as the OAS-M, the PITS, and the MGH Hairpulling Scale, have potential clinical utility with this population.

Of particular concern, many of the dimensional instruments appear to become less sensitive at more extreme levels, for several reasons. The oldest and most widely used measures in this domain (the BDHI and the BIS-11) were developed for research purposes and were, in large part, validated on university students, who differ considerably in age, level of education, and socioeconomic status from many clinical populations. Thus, these instruments do not always generalize well to clinical samples. Many of the self-report measures rely heavily on questions that ask subjects to make generalizations about relevant attitudes or behavioral patterns. According to a fairly large body of literature, highly impulsive and aggressive people have difficulties conceptualizing their own personal traits and, consequently, demonstrate poor insight into their own behavior.

Few of the scales focus on concrete behavioral manifestations of impulsive or aggressive traits. Such questions are of most interest to clinicians who work with these populations and are also likely to best identify high levels of impulsive and aggressive behavior. For example, many subjects may feel like slapping someone else, but the frequency with which they act on this impulse determines their true levels of impulsivity and aggression.

Therefore, additional assessment of concrete aggressive behaviors would still be needed for a complete evaluation. The scales should thus be used only with great caution for predicting future aggressive behavior and only in combination with other sources of information.

### Issues in Interpreting Psychometric Data

Limitations in the psychometric properties of most of these instruments hamper the interpretation of individual test scores. Few of the scales in this domain have standardized norms or cutoff scores. The STAXI is the only trait measure for which norms have been determined, and the SOGS is the only diagnostic measure for which a cutoff score has been determined. Similarly, most of the scales were validated on samples of limited size. Hence, it is difficult to interpret the clinical significance of individual scores.

The three scales that assess diagnostic categories are, by definition, more closely geared toward clinical phenomena than the other scales. They are more oriented toward assessing specific behavioral symptoms (e.g., time spent pulling hair in the past week) and should thus maintain sensitivity at high levels of clinical severity. Because both of the trichotillomania scales are fairly new and are in the preliminary stages of validation, no standardized norms or cutoff scores are available for these scales.

Other than the SOGS, which functions as the gold standard for its domain, there is no gold standard in determining the validity of any of these scales. For example, for the trichotillomania scales covered in this chapter, each scale uses its correlation with the other as the sole evidence of validity.

## GUIDE TO THE SELECTION OF MEASURES

All the instruments presented here may be of some use in clinical settings. For example, they can help provide a systematic assessment of baseline symptomatology and of change across treatment. In group settings, such as clinics, hospitals, and even large practices, these measures can be used to assess the impact of specific clinical factors (impulsivity and aggression) on a range of treatment variables, including treatment success, treatment compliance, rehospitalization, and therapeutic alliance. None of these instruments, however, should substitute for a thorough clinical evaluation, and most should be admin-

istered in conjunction with other measures. When possible, clinicians should use measures of a different format along with self-report measures. All the instruments in this chapter are especially appropriate for research purposes, for which sensitivity to variation in group means is most important.

For the purpose of measuring impulsivity as a state or trait that might cut across the diagnostic categories covered in this chapter and the entire spectrum of disorders with associated impulsive behavior (e.g., bipolar disorder, conduct disorder, borderline personality disorder, antisocial personality disorder, eating disorders, paraphilias, and substance use disorders), the only scale that might be applicable is the BIS-11. Although supporting data are currently lacking, the BIS-11 also may be useful in measuring change in an individual's impulsivity over time in response to treatment. The lack of norms and standardized scores limits its utility as a clinical assessment tool, but the BIS-11 has been shown to discriminate between impulsive and nonimpulsive groups.

Despite the lack of measures specifically designed to diagnose intermittent explosive disorder, several measures that might be helpful in the assessment of anger and aggression, two essential components of this disorder, are available. The self-report BDHI is the most widely known instrument for measuring anger and hostility, but its lack of standardized norms makes interpretation of individual scores difficult.

The STAXI, which focuses on modes of anger expression, is very well standardized and has detailed norms. It also has some utility in predicting stress-related physical conditions, such as hypertension. However, the STAXI has limited utility in populations with extreme levels of anger or aggression, such as subjects with antisocial personality disorder or prisoners, because it fails to measure the frequency of concrete, aggressive behaviors. The AIAQ, another self-report measure of anger and aggression, is more extensive and covers irritability, anger, and concrete aggressive behavior over three different time frames. However, the absence of norms, clear cutoff scores to assess diagnostic relevance, and standardized scores limits the clinical utility of both the STAXI and the AIAQ. The OAS-M is the only measure of aggression that actually assesses concrete aggressive behavior in detail; such an evaluation is generally of greatest interest to clinicians who treat aggressive patients.

For pathological gambling, the gold standard is the SOGS, although it has some significant limitations, including that it does not correspond exactly with th DSM-IV diagnosis of pathological gambling or take int account frequency of gambling behaviors. Although th two trichotillomania scales have limited validity and r liability data, they appear to be useful in clarifying th breadth and severity of clinical features. The choice b tween these scales depends primarily on the intende mode of administration; the PITS is clinician admini tered, whereas the MGH Hairpulling Scale is a self-repo measure.

None of the scales in this chapter was designed t predict the likelihood of future violence. The probabili of violent behavior is notoriously difficult to predict. Pe haps the best predictor of future violence is a history violence. As such, only the OAS-M, which assesses th frequency of various aggressive behaviors in the pa week, might contribute relevant information. Th 1-week time frame, however, may be overly restrictive i this case.

Instruments were selected for this chapter for the proven psychometric properties, wide use in the field, p tential clinical utility, or evident promise as up-and coming measures. Because of space limitations, sever instruments that assess aggression or relevant impulsiv behavior could not be included in this chapter. For tho assessing long-term aggressive behavior, the Brow Goodwin Life History of Aggression (Brown et al. 198 and the Life Time History of Aggression (Coccaro et a 1997) may be of interest. Two trichotillomania instru ments that were not included in this chapter may also b useful: the National Institute of Mental Health Trichr tillomania Scale (Swedo et al. 1989) and an adaptatio of the Yale-Brown Obsessive Compulsive Scal (Y-BOCS) (p. 572) (Stanley et al. 1993). The Y-BOC has also been adapted to measure compulsive buyin (Monahan et al. 1996).

## CURRENT STATUS AND FUTURE RESEARCH NEEDS FOR ASSESSMENT

The instruments that assess impulse-control disorders an related dimensions are for the most part in the preliminary stages of development. In general, more scales an increased psychometric data derived from larger an more varied samples are needed. More diagnostic instru ments are needed for all the impulse-control disorder

especially for pyromania and kleptomania. Both questionnaires and semistructured interviews would be useful; in both formats, items should assess concrete behavior in greater detail than do current instruments to improve sensitivity at high levels of impulsivity and aggression.

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# Barratt Impulsiveness Scale, Version 11 (BIS-11)

*E. Barratt*

## GOALS

The current version of the Barratt Impulsiveness Scale, Version 11 (BIS-11) (Barratt and Stanford 1995), and its predecessors were developed to assess impulsivity. Impulsivity is conceptualized as related to the control of thoughts and behavior and is broadly defined as acting without thinking. The BIS-11 looks at impulsivity in terms of three domains: Motor Impulsiveness, Nonplanning Impulsiveness, and Attentional Impulsiveness. This and previous versions of the BIS were designed primarily as research instruments to aid in the description of impulsivity in psychiatrically healthy individuals and to explore the role of impulsivity in psychopathology.

## DESCRIPTION

The BIS-11 is a self-administered questionnaire with 30 items scored on a 4-point scale ranging from 1 = rarely/never to 4 = almost always/always. Sample items are provided in Example 31–1. Possible scores range from 30 to 120. There are no standardized norms for the BIS-11, but the total score averaged 63.8 ± 10.2 in a sample of 412 undergraduates, 69.3 ± 10.3 in a sample of 164 psychiatric inpatients with substance abuse problems, 71.4 ± 12.6 in 84 general psychiatric inpatients, and 76.3 ± 11.9 in 73 male prison inmates.

## PRACTICAL ISSUES

Administration time is not specified but is estimated to be about 10–15 minutes. The test requires a fifth-grade reading level and is intended for individuals ages 13 and older. The test is printed in full in the chapter by Barratt and Stanford (1995). For additional information about the measure, the author can be contacted at the following address:

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**EXAMPLE 31–1 ■ Sample items from the Barratt Impulsiveness Scale, Version 11**

I squirm at plays or lectures.

I don't "pay attention."

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# Handbook of Psychiatric Measures


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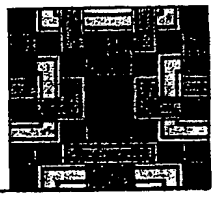
CHAPTER 24



# Mood Disorders Measures

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*Jacqueline Samson, Ph.D.*

## INTRODUCTION

### Major Domains

This chapter covers 13 scales that may help the clinician in the assessment and management of mood disorders. Although only one of the included measures has been specifically designed to assist the clinician in making a DSM-IV diagnosis of mood disorder, the scales measure symptoms that are characteristic of the various mood disorders contained in DSM-IV. Like DSM-IV, the scales are divided into those that measure depressive symptoms and those that measure manic symptoms. Because hypomania is defined in DSM-IV as a less severe form of mania in terms of duration and consequent impairment, the so-called mania scales may be relevant in measuring hypomania as well.

### Organization

This chapter is divided into three sections (see Table 24–1). The first section presents seven depression rating scales that were developed for a general psychiatric population (inpatient or outpatient). The second section contains three scales that measure mania or hypomania. The final section contains three depression scales that were developed for use in special populations, specifically one scale each for use in postpartum women, elderly people, and the medically ill.

### Relevant Measures Included Elsewhere in the Handbook

Measures relating to the diagnosis of mood disorders in conjunction with other psychiatric disorders are included elsewhere in this manual. See, for example, the mood disorders section of the Structured Clinical Interview for DSM-IV (SCID) (p. 49) and the Schedule for Affective Disorders and Schizophrenia (SADS) (p. 58). Scales for evaluating mood disorders in children are included in Chapter 18, "Symptom-Specific Measures for Disorders Usually First Diagnosed in Infancy, Childhood, or Adolescence." Chapter 23, "Psychotic Disorders Measures," includes the Calgary Depression Scale for Schizophrenia (CDSS) (p. 504), which was designed expressly for the assessment of symptoms of major depressive episode in patients with a diagnosis of schizophrenia.

Symptom measures that evaluate multiple emotional or behavioral states (e.g., vitality and anxiety), such as the Profile of Mood States (POMS) (McNair et al. 1971), are not included in this section because we are reviewing specialized scales that detect or rate the severity of depression and manic episodes. Finally, instruments that require administration by an inpatient team, such as the Beigel Mania Rating Scale (BMRS) (Beigel et al. 1971), are not included in this chapter because they are not intended for use in an office-based setting.

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TABLE 24–1 ■ Mood disorders measures

| NAME OF MEASURE | DISORDER OR CONSTRUCT ASSESSED | FORMAT | PAG |
|---|---|---|---|
| **Depression rating scales for general psychiatric or community populations** | | | |
| Beck Depression Inventory (BDI)<br>First revision (BDI-IA)<br>Second revision (BDI-II) | Severity of depressive symptoms | Self-report; 21 items | 519 |
| Center for Epidemiologic Studies Depression Scale (CES-D)* | Severity of depressive symptoms in community populations | Self-report; 20 items | 523 |
| Hamilton Rating Scale for Depression (Ham-D) | Severity of depressive symptoms in patients with primary depressive illness | Interviewer-administered scale; 17 items | 526 |
| Inventory of Depressive Symptomatology (IDS)*<br>Self-report version (IDS-SR)<br>Clinician-administered version (IDS-C) | Severity of signs and symptoms of depression (includes all DSM criteria items) | Self-report (IDS-SR) or clinician-administered semistructured interview (IDS-C); 28- and 30-item versions | 529 |
| Montgomery-Asberg Depression Rating Scale (MADRS) | Severity of depressive symptoms | Interviewer-administered checklist; 10 items | 531 |
| Raskin Scale (Three-Area Severity of Depression Scale)* | Severity of depression in three areas: subjective experience, behavioral manifestations, and secondary signs of depression | Interviewer-rated scale; 3 items | 533 |
| Zung Self-Rating Depression Scale (Zung SDS)* | Severity of depressive symptoms | Self-report; 20 items | 534 |
| **Mania rating scales** | | | |
| Clinician Administered Rating Scale for Mania (CARS-M)* | Severity of manic and psychotic symptoms | Clinician-administered scale; 15 items with question prompts | 537 |
| Internal State Scale (ISS)* | Severity of manic symptoms (conceptualized as activation, perceived conflict, and well-being) and depressive symptoms in patients with bipolar disorder | Self-report; 17 items | 539 |
| Young Mania Rating Scale (YMRS)* | Severity of manic symptoms; relapse or recurrence of manic symptoms | Clinician-administered checklist; 11 items | 540 |
| **Depression rating scales for use in special populations** | | | |
| Edinburgh Postnatal Depression Scale (EPDS) | Screening test for postpartum depression | Self-report; 10 items | 542 |
| Geriatric Depression Scale (GDS)* | Screening test for depression in elderly people | Self-report; 30 items | 544 |
| Hospital Anxiety and Depression Scale (HADS) | Severity of depression and anxiety in medically ill patients | Self-report; 14 items | 547 |

*Measure is included on the CD-ROM that accompanies this handbook.

## USING MEASURES IN THIS DOMAIN

### Goals of Assessment

The most common goal of assessment is to measure the severity of depressive or manic symptoms, in terms of both the severity of individual symptoms and the total number of mood-related symptoms that have been present. Measuring severity is particularly useful in setting a baseline so that repeated administration during the course of treatment may be used to document improvement.

Recent changes in medical care service provision have resulted in larger numbers of patients with mood disorders being treated in nonpsychiatric settings, such as primary care and nursing home facilities, so that instruments specifically developed to screen for mood disorders in such settings are needed. Unfortunately, generic depression symptom severity indexes may have less than optimal performance in populations such as patients with general medical illness, postpartum women, and elderly individuals. In particular, most depressive scales include items for rating the presence of somatic symptoms, such as insomnia or fatigue. In these populations, the high incidence of somatic symptoms unrelated to depression may lead to an overdiagnosis of depression by inappropriately counting these symptoms as being due to a depressive syndrome. Hence, special scales validated specifically in these populations have been developed: the Geriatric Depression Scale (GDS) for use with elderly people in nursing home settings, the Hospital Anxiety and Depression Scale (HADS) for use in primary care or hospital settings, and the Edinburgh Postnatal Depression Scale (EPDS) for use with postpartum patients in primary care settings.

Three of the depressive symptom severity scales included in this chapter (the Beck Depression Inventory [BDI], the Center for Epidemiologic Studies Depression Scale [CES-D], and the Zung Self-Rating Depression Scale [Zung SDS]) are also used to screen for depressive illness in the community or in general medical populations. This application requires a two-stage approach; the first-stage screen selects persons likely to have a mood disorder, and these patients then go on to a second-stage clinical diagnostic interview. This strategy is cost-effective because paper and pencil questionnaires may be used to identify a smaller number of persons for a clinician-administered diagnostic interview.

### Implementation Issues

The self-report instruments reviewed in this chapter require that individuals be able to read at a minimal reading level and that they speak the language used in one of the translations of the instrument. The use of these instruments is also limited in patients who have cognitive impairment. Some experts believe that self-report instruments perform less well in patients with severe illness.

The clinician-administered scales range from checklists to structured interviews, and all but the Montgomery-Asberg Depression Rating Scale (MADRS) recommend that clinicians administering the scale be trained. For some scales (e.g., the Hamilton Rating Scale for Depression [Ham-D]), it is also suggested that the clinician using the scale have training in psychiatry or psychology. Most of the clinician-administered scales do not rely on the use of additional information obtained outside the clinical interview; however, in some instances (e.g., in patients with poor insight), such information may be beneficial.

All of the depressive rating scales have been used as screens and can indicate the presence of depressive symptoms. However, unless the screen were used in a patient with an earlier determined diagnosis of depressive disorder, the clinician would still need to completely assess the patient before diagnosing depressive disorder (i.e., the measures cannot be used to diagnose depression).

None of the depression scales included in this chapter provides good coverage of psychotic symptoms in depression, although the Ham-D includes some hints at psychotic symptoms in the severity anchors.

### Issues in Interpreting Psychometric Data

There is no gold standard for determining whether an individual has a mood disorder. In many instances, the construct of *depression* or *mania* used by the authors was defined by diagnostic criteria in DSM-IV (e.g., the Inventory of Depressive Symptomatology [IDS]) and by standardized diagnostic instruments such as the SADS (p. 58) (e.g., the Clinician Administered Rating Scale for Mania [CARS-M]). In some instances, however, the author's clinical experience was used to select items pertaining to the construct (e.g., the Ham-D, the MADRS, and the Young Mania Rating Scale [YMRS]). In depression scales developed before 1980, this method of selecting items resulted in an overemphasis on symptoms of endogenous depression and less inclusion of atypical

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symptoms such as hyperphagia and hypersomnia. This overemphasis on endogenous symptoms may thus have implications for identifying subpopulations of individuals with mood disorders (i.e., those with atypical or melancholic depression) and also for the comprehensiveness with which the instrument covers the construct. For example, the Ham-D is less comprehensive than newer scales such as the IDS in its rating of the severity of atypical depressive illnesses.

In several scales, we note problems in distinguishing depressive symptoms from anxiety symptoms. The relationship between depression and anxiety is reflected by large correlations between the depression symptom severity measure and measures of anxiety. This relationship may contribute to the low specificity and poor positive predictive values found in studies of screening instruments. It is a complicated problem because research data suggest that approximately 60% of depressed individuals show comorbid anxiety symptoms. Other studies suggest that a subgroup of patients may cycle between anxiety and depression or may show a baseline of anxiety symptoms that periodically escalate and show comorbidity with superimposed depressive episodes. Thus, the distinction between these two disorders is not clinically clear. Data on this problem are included, when available, in discussions of the specific measures.

Studies have found a range of estimates of sensitivity and specificity, depending on the base rates of depression in the sample screened and the comorbid medical and psychiatric conditions that are present. Again, further work is needed to maximize the screening efficiency of these measures, but we include examples of the best available.

## GUIDE TO THE SELECTION OF MEASURES

The selection of a specific measure depends on when the measure is to be used, the type of scale to be used, and the application. Clinicians should consider three factors in selecting measures: 1) cost, 2) time, and 3) coverage. One might consider doing a cost-benefit analysis of the measure to determine whether the output of the instrument (i.e., whether the measure captures what the clinician wishes to capture) is worth the time and effort involved in its administration. Relative cost versus coverage and validity should also be weighed when choosing between self-report and clinician-administered questionnaires. Advantages of self-report formats include time savings and the ability of clinicians to routinely track a symptom without asking about it specifically (e.g., suicidal ideation).

The screening instruments reviewed in this chapter were developed either for use in nonpsychiatric populations (the CES-D, the EPDS, the HADS, and the GDS) or for measuring illness severity in previously diagnosed populations (the Ham-D, the Raskin Scale, the BDI, the MADRS, the Zung SDS, the CARS-M, and the Internal State Scale [ISS]). A problem with some screening measures, such as the CES-D and the EPDS, is that rather than specifically selecting for depression, they identify persons who show general distress. For example, follow-up interviews suggest that individuals with other conditions, such as anxiety disorders, may also screen positive with the CES-D and the EPDS. Data representative of these problems are covered in the sections on three instruments (the CES-D, the BDI, and the Zung SDS). Furthermore, scales such as the HAD, the BDI, the MADRS, the GDS, and the EPDS rely less on somatic symptoms to screen for or rate mood and are more appropriate for postpartum or geriatric populations or those who have general medical illnesses.

All of the scales in this chapter that assess symptom severity show good reliability and validity when used in populations of patients with diagnosed mood disorders. Thus, most instruments are good indicators of symptom change over time and are highly useful for monitoring the comparative efficacy of treatments over time or in documenting outcomes in populations of patients treated in a group practice or other outpatient settings. Different measures cover different sets of depressive symptoms. For example, atypical symptoms are not assessed effectively with the standard 17-item Ham-D, the BDI, the Zung SDS, or the MADRS. The IDS, which queries about atypical symptoms, may be more helpful for measuring the severity of atypical symptoms. On the other hand, endogenous symptoms are adequately addressed by all of the depressive symptom scales evaluated. The BDI (version II), the IDS, and the CARS-M include both DSM-III-R and DSM-IV criteria and thus provide complete data regarding change in individual DSM symptoms. Measures that include DSM criteria may be helpful in managed-care settings in which information on improvement in DSM-IV symptoms is often required.

Although the screening and measuring tools reviewed in this chapter can be helpful in identifying mood disorders, they cannot establish a diagnosis. Clinical interview and structured clinical diagnostic instruments should also be employed to obtain accurate diagnoses for these patients

## CURRENT STATUS AND FUTURE RESEARCH NEEDS FOR ASSESSMENT

Although there are a plethora of instruments for measuring the severity and existence of depressive disorders, relatively few validated instruments identify and evaluate mania and hypomania. Further, relatively small populations have been used to validate the existing instruments. Thus, future research should focus on developing instruments and techniques to evaluate mood states in patients with mania and hypomania. Inclusion of questions regarding the depressed phase and the manic phase of illness would also enhance the utility of instruments for patients with bipolar disorder.

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# Beck Depression Inventory (BDI)

*A. T. Beck and R. A. Steer*

## GOALS

The Beck Depression Inventory (BDI) (Beck et al. 1961) was developed to measure the behavioral manifestations of depression in adolescents and adults. It was designed to standardize the assessment of depression severity in order to monitor change over time or to simply describe the illness. The items of the BDI were originally derived from observations of depressed patients made during the course of psychoanalytic psychotherapy. Attitudes and symptoms that appeared to be specific to this group of patients were described by a series of statements, and a numerical value was assigned to each statement.

In its original form, 21 behavioral manifestations were covered, each area represented by four or five statements describing symptom severity from low to high. Subjects were asked to identify the statement that best described their feelings "right now." Items were then scored and summed to obtain a total score for depressive symptom severity. An abbreviated version containing 13 items was published in the Early Clinical Drug Evaluation Program (ECDEU) assessment manual (Guy 1976). In 1978, the full scale was revised (BDI-IA) to eliminate duplicate severity descriptors and to reword certain items. In addition, the time frame for assessment was lengthened to the "last week, including today." In 1993, the

# Handbook of Psychiatric Measures


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